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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,523	02/28/2002	Robert D. Klein	MES-01-CON2	3478
26619	7590	07/01/2004	EXAMINER	
DELTAGEN, INC. 1031 Bing Street San Carlos, CA 94070			LEFFERS JR, GERALD G	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,523

Applicant(s)

KLEIN ET AL.

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/28/2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a preliminary amendment, filed 2/28/2002, in which claims 1-50 were cancelled and new claims 51-61 were added. Claims 51-61 are pending in the instant application and are under consideration.

Specification

At page 12, line 13, of the instant specification there is a reference to U.S. Application Serial No. 07/847,298. This reference is improper as there is no application assigned to that number. Office records indicate that this number was missassigned and does not correspond to any application. Therefore, it would be remedial to amend the instant specification to remove reference to U.S. Application Serial No. 07/847,298.

Information Disclosure Statement

Receipt is acknowledged of an information disclosure statement (IDS) filed 2/28/2002. The signed and initialed PTO Form 1449 corresponding to the IDS has been mailed along with this action. It is noted that U.S. Patent Serial Number 07/847,298 does not correspond to an actual file in the Office records as the number was missassigned. Therefore, this entry on the PTO Form 1449 has been crossed off as not considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 51-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51 and 57 are vague and indefinite in that the metes and bounds of the phrase “wherein the first region and second region homologously recombine with the target gene or sequence” are unclear. The claims are directed to producing a targeting construct and yet the cited phrase appears to indicate an additional methods step requiring the use of the construct. As written, it is unclear whether the cited phrase necessarily specifies an additional methods step or is merely “characterized by” type language meant to specify a functional property of the targeting construct. It would be remedial to amend the claim to clearly delineate between the two possibilities.

Claim 57 is vague and indefinite in that the metes and bounds of the phrase “a first polynucleotide sequence corresponding to a target gene or sequence from a circular plasmid library” are unclear. First, it is unclear as the claim is written whether the term “target” refers to both the gene and the sequence from the plasmid library. Second, it is unclear if the target gene necessarily comes from the circular plasmid library or not.

Claims 56 and 61 recite the limitation that the screening marker located on the targeting construct “is a fluorescent protein”. It is unclear how a targeting construct (i.e. nucleic acid) can comprise a fluorescent protein. It would be remedial to amend the claims to read, “encodes a fluorescent protein”.

Claim 59 is vague and indefinite in that the metes and bounds of the phrase “oligonucleotide primers that are at least 12 nucleotides in length and have a 5’ sequence lacking

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one type of base" are unclear. How close to the 5' end does the sequence have to be in order to satisfy the limitation of being a "5'" sequences? For example, does the sequence have to be 5'-terminal, as is implied by the term "5' sequence" in order to satisfy the limitation? It would be remedial to amend the claim language to clearly indicate the minimal structural requirement for the primer with regard to the location of the "5' sequence" lacking one type of base.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 51-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 61-82 of copending Application No. 09/885,816. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The instant claims are directed to ligation independent methods for generating a targeting construct comprising a positive selection marker flanked by regions of homology to a target gene or target sequence. The regions of homology can be obtained from a circular plasmid library. The neomycin resistance gene is an example of the positive selection marker recited in the

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rejected claims. The targeting construct can further comprise a screening marker (e.g. a sequence encoding a fluorescent protein).

The claims of the '816 application are directed to methods of producing a targeting construct. The methods of the '816 application are more specific than the instant application in that: (i) the practitioner provides a first sequence homologous to a target sequence (e.g. from a circular plasmid library), (ii) generates two fragments of the first sequence that are complementary to a target sequence, (iii) provides a vector having a gene encoding a positive selection marker, and (iv) uses ligation independent cloning to insert the two fragments comprising sequences complementary to a target sequence into the vector such that the two different fragments flank the gene encoding the positive selection marker.

The claims from the '816 application are specific embodiments of the more broadly directed claims of the instant application.. Thus, the claims of the '816 application anticipate, and necessarily make obvious, the generic claims of the instant application. Further, patents issued on the instant claims and the claims of the '816 application would, improperly, result in the possible harassment of a third party by multiple assignees if the rights to the issued claims from either application were sold to another party.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. However, it is noted that a Notice of Allowance has been mailed in the '816 application (5/6/2004) and that this grounds of rejection will no longer be provisional in nature as soon as the '816 application issues to patent.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

ggl


GERRY LEFFERS
PRIMARY EXAMINER